



**National  
Registration  
Authority**

For Agricultural & Veterinary Chemicals

First Floor, Industry House, National Circuit, Barton ACT  
PO Box 240, Queen Victoria Terrace, Canberra ACT 2600 Australia  
Tel: (06) 272 5158 Fax: (06) 272 4753

---

**Public Release Summary**

**TRINEXAPAC--ETHYL**

**IN THE PRODUCT  
PRIMO 250 EC TURF GROWTH REGULATOR**

This document is published by the  
National Registration Authority for  
Agricultural and Veterinary Chemicals.  
For further information, please contact:

Dr Ronald Eichner  
National Registration Authority  
PO Box 240  
Queen Victoria Terrace  
PARKES ACT 2600

Ph: (06) 2725248  
Fax: (06) 2723218

## **FOREWORD**

*The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent Statutory Authority with responsibility for the assessment and approval of agricultural and veterinary chemical products prior to sale and use in Australia.*

*In undertaking this task, the NRA works in close cooperation with advisory agencies including the Department of Human Services and Health (Chemical Safety Unit), the Commonwealth Environment Protection Agency (CEPA), the National Occupational Health and Safety Commission (Worksafe Australia) and State Departments of Agriculture and Health.*

*The NRA has a policy of encouraging openness and transparency in its activities and seeking community involvement in decision making. The publication of Public Release Summaries for all products containing new active ingredients is a part of that process.*

*The information and technical data required by the NRA in order to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in the document "Requirements for Clearance of Agricultural and Veterinary Chemical Products" which can be obtained from the NRA.*

*This Public Release Summary is intended as a brief overview of the assessment that has been completed by the NRA and advisory agencies. The document has been deliberately presented in a manner that is likely to be informative to the widest possible audience thereby encouraging public comment. The publication of more technical information to accompany Public Release Summaries is planned for the future.*

*As a relatively new organisation, the NRA would welcome comment on the usefulness of this document and suggestions for further improvement. Comments should be forwarded to The National Registration Manager, National Registration Authority for Agricultural and Veterinary Chemicals, PO Box 240, Queen Victoria Terrace, Parkes, ACT, 2600.*

**ABBREVIATIONS AND ACRONYMS WHICH MAY BE USED IN THIS DOCUMENT**

|                        |   |
|------------------------|---|
| <b>ADI</b>             | Acceptable Daily Intake (for humans)  |
| <b>CSU</b>             | Chemical Safety Unit (of the Department of Human Services and Health)                                       |
| <b>d</b>               | Day   |
| <b>EC<sub>50</sub></b> | Concentration at which 50% of the test population of fish are immobilised                                   |
| <b>EUP</b>             | End Use Product   |
| <b>F<sub>0</sub></b>   | Original Parent Generation  |
| <b>h</b>               | Hour  |
| <b>HPLC</b>            | High Performance Liquid Chromatography  |
| <b>id</b>              | Intradermal   |
| <b>ip</b>              | Intraperitoneal   |
| <b>im</b>              | Intramuscular   |
| <b>iv</b>              | Intravenous   |
| <b>In Vitro</b>        | Outside the living body and in an artificial environment  |
| <b>In Vivo</b>         | Inside the living body of a plant or animal   |
| <b>Kg</b>              | Kilogram  |
| <b>L</b>               | Litre   |
| <b>LC<sub>50</sub></b> | Concentration that kills 50% of the test population of organisms  |
| <b>LD<sub>50</sub></b> | Dosage of chemical that kills 50% of the test population of organisms                                       |
| <b>m</b>               | Metre   |
| <b>mg</b>              | Milligram   |
| <b>mL</b>              | Millilitre  |
| <b>MRL</b>             | Maximum Residue Limit (a legal limit)   |
| <b>MSDS</b>            | Material Safety Data Sheet  |
| <b>ng</b>              | Nanogram  |
| <b>NHMRC</b>           | National Health and Medical Research Council  |
| <b>NOEC/NOEL</b>       | No Observable Effect Concentration/Level  |
| <b>NRA</b>             | National Registration Authority for Agricultural and Veterinary Chemicals                                   |
| <b>po</b>              | Oral  |
| <b>ppb</b>             | parts per billion   |
| <b>ppm</b>             | parts per million   |
| <b>s</b>               | Second  |
| <b>sc</b>              | Subcutaneous  |
| <b>SUSDP</b>           | Standard for the Uniform Scheduling of Drugs and Poisons  |
| <b>T-Value</b>         | A value used to determine the First Aid Instructions for chemical products that contain two or more poisons |
| <b>TGAC</b>            | Technical Grade Active Constituent  |
| <b>WDG</b>             | Water Dispersible Granule   |
| <b>WHP</b>             | Withholding Periods   |

## EXECUTIVE SUMMARY

### Introduction

The purpose of this document is to provide a summary of the data reviewed and an outline of regulatory considerations for the proposed clearance and registration of the chemical trinexapac-ethyl in the product PRIMO 250 EC as a growth regulator for use on turf. Use in NSW, Vic, Qld, WA, SA, and NT is proposed.

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) invites public comment before deciding whether to proceed to approve this product for use in Australia.

The NRA has completed an assessment of the data submitted by the applicant in support of this use of trinexapac-ethyl and has provided the following information for public comment:

### Agricultural Aspects

Trinexapac-ethyl, belonging to the chemical class of cyclohexanediones, is a turf growth regulator that should help alleviate the shortage of products specifically targeted to the professional turf management industry. Trinexapac-ethyl suppresses cellular and internodal elongation of turf grass by inhibiting gibberellic acid biosynthesis.

The product PRIMO 250 EC is an emulsifiable concentrate containing 250g/L trinexapac-ethyl, together with two surfactants, dissolved in liquid hydrocarbons. The product will be applied to amenity turf, as a low volume spray, at rates ranging from 1 to 4 L/ha and as a high volume spray at 10 to 400 mL/ha, as detailed in the directions for use on product label.

Efficacy trials carried out in Australia indicated good suppression of grass growth with little or no effect on dicotyledenous species. Certain varieties of grass showed a high sensitivity to trinexapac-ethyl and use on these species is not recommended. Advantages of trinexapac-ethyl include its potential to reduce the amount of mowing required and an ability to preserve lawn edges thereby reducing the need to apply knockdown herbicides.

### Environmental Aspects

Trinexapac-ethyl is expected to become mainly associated with the soil following application, where it is strongly bound and then subject to microbial degradation. In the event that spray drift contacts water, rapid dissipation through photolysis and hydrophobic partitioning processes will result.

Trinexapac-ethyl is likely to have low to moderate persistence in the soil compartment, limited persistence in the aqueous phase of the aquatic compartment, and moderate persistence in sediment. Trinexapac-ethyl and its primary metabolites are unlikely to leach to groundwater.

The ecotoxicological profile of trinexapac-ethyl generates no concern for fauna studied (birds, fish, cladocerans, bees and rodents) with the exception of mysid shrimp and fish larvae towards which trinexapac-ethyl is moderately toxic. However, it is highly toxic to bluegreen algae and higher aquatic plants. The proposed use pattern is not expected to entail significant aquatic exposure, as most of the applied dose will be taken up by turfgrass and metabolised. Use as proposed is not expected to give rise to significant environmental contamination or damage to non-target organisms.

## **Public Health Aspects**

### **Toxicology**

Trinexapac-ethyl is of low acute oral, dermal and inhalational toxicity. It has slight skin and eye irritation potential in rabbits, and is not a skin sensitiser in guinea pigs. The formulation for PRIMO 250 EC is expected to be of low acute oral and inhalational toxicity, and to have potential to cause moderate skin and eye irritation.

In repeat-dose studies, toxic effects were noted in the stomach, liver, kidney, adrenals, heart, brain and thymus at high doses. There were marginal increases in the incidence of tumours in the stomach and skin of rats at high oral dose rates, but these effects are probably not relevant to humans considering the low exposures of short duration expected to result from the use of products containing trinexapac-ethyl. There was no evidence of a potential to alter fertility, cause birth defects or damage genetic material (DNA).

### **Residues in Food Commodities**

Based on an assessment of the toxicology and the fact that there should be no dietary intake of residues of trinexapac-ethyl, it was considered that there should be no adverse effects on human health from the use of PRIMO 250 EC for the regulation of turf growth according to label instructions.

### **Occupational Health and Safety**

PRIMO 250 EC presents minimal safety risk to workers when handled according to instructions on the label and the MSDS. The risk of developing significant acute and chronic health effects from occupational exposure is low.

**TABLE OF CONTENTS**

|   | PAGE |
|---|------|
| 1. INTRODUCTION                                 |      |
| - Applicant                                     | 7    |
| - Product details                               | 7    |
| - Overseas registration status                  | 7    |
| 2. PROPERTIES OF THE CHEMICAL ACTIVE INGREDIENT |      |
| 3. AGRICULTURAL ASSESSMENT                      |      |
| - Justification for use                         | 8    |
| - Proposed use pattern                          | 8    |
| - Evaluation of efficacy                        | 9    |
| - Phytotoxicity                                 | 9    |
| 4. ENVIRONMENTAL ASSESSMENT                     |      |
| - Environmental Fate                            | 9    |
| - Environmental Effects                         | 10   |
| - Environmental Hazards                         | 11   |
| 5. PUBLIC HEALTH AND SAFETY ASSESSMENT          |      |
| - Evaluation of Toxicology                      | 12   |
| - Potential for Residues in food for humans     | 15   |
| - Public health standards                       | 15   |
| 6. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT    | 15   |
| 7. SUGGESTED FURTHER READING                    | 16   |
| 8. APPENDIX I Draft Label                       |      |

## INTRODUCTION

The purpose of this document is to provide the public with a summary of the data reviewed and an outline of the regulatory considerations for the proposed application of the chemical trinexapac-ethyl as a growth regulator on turf, and to seek public comment prior to the chemical product being approved for use in Australia.

Comments should be received by 1994 and sent to:

Dr Ronald Eichner  
Manager, Agricultural Registration  
NRA  
PO Box 240  
Queen Victoria Terrace ACT 2600  
TEL: (06) 271 5248  
FAX: (06) 272 3218

### **Applicant**

Ciba-Geigy Australia Ltd has applied for clearance and registration of a turf growth regulator product containing a new active constituent, trinexapac-ethyl, a cyclohexanedione plant growth regulator that reduces cellular and internodal elongation by inhibiting gibberellic acid biosynthesis.

### **Product Details**

Trinexapac-ethyl will be marketed under the product name PRIMO 250 TURF GROWTH REGULATOR as an emulsifiable concentrate formulation containing 250 g/L of active constituent.

PRIMO 250<sup>l</sup> TURF GROWTH REGULATOR will be formulated locally from imported active ingredient.

Ciba-Geigy Australia Ltd intends to market PRIMO 250 EC TURF GROWTH REGULATOR in all States for use on amenity turf.

### **Overseas Registration Status**

Products containing trinexapac-ethyl are registered in the following countries: Switzerland, France, South Africa and USA.

## PROPERTIES OF THE CHEMICAL ACTIVE INGREDIENT

The chemical active ingredient trinexapac-ethyl is manufactured in Switzerland and has the following properties:

|                                      |   |
|--------------------------------------|---|
| Common name:                         | trinexapac-ethyl (ISO)  |
| Chemical name:                       | 4-(cyclopropyl- $\alpha$ -hydroxy-methylene)-3,5,-dioxo-cyclohexanecarboxylic acid ethylester |
| Product name:                        | PRIMO 250 EC TURF GROWTH REGULATOR  |
| CAS registry number:                 | 95266-40-3  |
| Empirical formula:                   | C <sub>13</sub> H <sub>16</sub> O <sub>5</sub>  |
| Molecular weight:                    | 240.21  |
| Physical form:                       | liquid  |
| Colour:                              | yellow to red-brown   |
| Odour:                               | slightly sweet  |
| Melting Point:                       | >270 °C   |
| Density:                             | 1.215 g/cm <sup>3</sup> at 20°C   |
| Octanol/water partition coefficient: | Log P <sub>ow</sub> = 2.44. at pH 5.3   |
| Vapour pressure:                     | 2.16 x 10 <sup>-3</sup> Pa at 25°C  |
| Structural Formula:                  |   |

## AGRICULTURAL ASSESSMENT

### Justification for Use

The product has a high potential in situations, where turf grass is grown. Use of trinexapac will reduce the amount of mowing required on a lawn area and may preserve lawn edges reducing the need to apply knockdown herbicides. Situations where it may be used include golf courses, sports ovals parks and extensive grass areas such as airports, industrial areas and road sides. State efficacy reviewers have commented that there is a need for a plant growth regulator in the amenity turf management as the cost of maintaining turf areas is becoming prohibitive for many local councils and sporting clubs.

### Proposed Use Pattern

The product is to be mixed with water and intended for application to actively growing turf, between 1 and 3 days after mowing. The label advises that the product

should not be applied if rain is expected within 1 hour, and irrigation should be withheld for the same period after application.

The rate of usage will depend on the quality of turf area to be managed. The label includes specific instructions for high quality and low maintenance turf areas. For high quality turf (e.g. fairways, ovals and well maintained lawns) rates towards the lower end of the rate range are recommended. For low maintenance turf (e.g. parks, roadsides and general grass areas), rates towards the higher end of the rate range are recommended.

### **Evaluation of Efficacy**

A series of small scale replicated trials were conducted throughout Australia to evaluate the efficacy and safety of trinexapac-ethyl as an emulsifiable concentrate containing 250g/L active ingredient (ai). It was found that trinexapac-ethyl applied at rates from 250 gai/ha to 2000gai/ha is effective in reducing the leaf and stem growth of all grass species tested.

Trials were started in 1988/89 and have been conducted on a range of turf grass species including couch, kikuyu, perennial rye grass, fescue, Kentucky blue grass and bentgrass.

### **Phytotoxicity**

The susceptibility of grasses to trinexapac-ethyl varies across species with some (wintergrass, Kentucky blue grass and buffalo grass) considered too sensitive to be treated at the current use rate. However, activity against dicotyledonous plants is limited. This is consistent with the selectivity of the cyclohexanedione herbicides which are active against grasses.

## **ENVIRONMENTAL ASSESSMENT**

### **Environmental Fate**

Trinexapac-ethyl is rapidly absorbed by foliage and translocated to the growing points, where it inhibits gibberellic acid biosynthesis, thereby reducing cellular and internodal elongation. Grass growth is slowed, reducing mowing and maintenance requirements. Minor residues that are not taken up by vegetation are expected to become associated with interstitial water in the soil. Trinexapac-ethyl is mobile but undergoes ready mineralisation in soils via a range of metabolites.

#### Degradation rates and routes

Abiotic hydrolysis of trinexapac-ethyl generates the corresponding carboxylic acid, but only proceeds at significant rates at alkaline pH. Photolysis is rapid, both in

solution and on the surface of soil, and involves ester hydrolysis and cleavage of the six and three membered rings.

Aerobic soil metabolism of trinexapac-ethyl initially involves ester hydrolysis, which has a half-life in the order of one day. The acid so generated has a half-life of about one week in soil. The tricarballoylate metabolite formed in soils from cleavage of the cyclohexane ring has a half-life of about one month.

Anaerobic soil degradation primarily involves hydrolysis to the acid, but is much slower (estimated half-life 10-25 d). Trinexapac-acid appears stable in anaerobic soils.

#### Metabolites

The primary metabolites are trinexapac-acid, which forms almost quantitatively soon after application, and open chain intermediates from cleavage of the six membered ring. The latter transform to the ethyl ester of tricarballoylic acid, which never exceeds 10% of applied. Carbon dioxide is a major metabolite, reaching about 50% of applied after 3 months in soil.

#### Mobility

Conventional adsorption/desorption tests indicate that trinexapac-ethyl and its acid metabolite sorb rather weakly to soils and are moderately to highly mobile. Significant leaching was observed on soil columns, particularly where infiltration was rapid. However, leaching is much less pronounced under field conditions because of the rapid metabolism that occurs, as evidenced by results from field dissipation studies on turf and bare soil.

The moderate vapour pressure suggests a potential for volatilisation, but this was not borne out by experiment. Limited volatilisation losses (less than 1%) were observed from foliage, but trinexapac-ethyl was well retained by soil because of its acidic properties.

#### Accumulation and bioaccumulation

Trinexapac-ethyl is a hydrophilic cyclohexanedione plant growth regulator that dissipates from soil principally by microbial metabolism. It and its metabolites are not expected to accumulate in soils or biota because of their hydrophilicity and limited persistence. The latter property should ensure that residues do not contaminate groundwater.

#### **Environmental Effects**

Results from acute oral and dietary studies on mallards and bobwhite indicate trinexapac-ethyl to be practically nontoxic to birds. Isolated mortalities in the dietary tests did not appear to be treatment related, and all surviving birds remained in good

health. Similarly, isolated deaths occurred but general behaviour, health, bodyweights and food consumption remained unimpaired in mallards and bobwhites to which trinexapac-ethyl was administered in the diet for 22 weeks at levels to 600 ppm. These tests provided no evidence of any significant adverse effects on reproductive capacity.

Acute tests on five species of fish indicate that trinexapac-ethyl is slightly toxic to practically nontoxic to fish, with LC50s between 35 and 180 ppm. Affected fish were observed to become sluggish and to swim erratically. The no-effect concentration for all fish was in the order of 30 ppm. Daphnids exhibited similar sensitivity.

Studies on marine organisms indicate that trinexapac-ethyl is slightly to practically non-toxic to oysters, and moderately toxic to the highly sensitive marine species, mysid shrimp, under conditions of acute exposure.

Chronic toxicity to fathead minnow embryos and larvae was investigated for 35 days (30 days post-hatch) in a flow-through system. Hatching was unaffected at the highest concentration tested of 3 ppm, but survival to the end of the test period dropped by about 10% compared with controls. Growth at termination provided the most sensitive indicator of toxicity, being reduced at concentrations of 0.8 ppm and above. The no-effect concentration was 0.41 ppm. Based on mortality, trinexapac-ethyl would appear to be moderately toxic to fathead minnow larvae under conditions of chronic exposure.

A statistically significant reduction in reproduction was observed among daphnids exposed for 21 days to 42 ppm trinexapac-ethyl under flow-through conditions. Parental growth reduction, measured as dry weight, was the most sensitive indicator of chronic toxicity, becoming apparent at concentrations of 21 ppm. Trinexapac-ethyl has slight chronic toxicity to daphnids.

Phytotoxicity tests were conducted under static renewal conditions on a range of aquatic vegetation. Results indicate that trinexapac-ethyl is highly toxic to duckweed and bluegreen algae, and slightly toxic to marine and freshwater diatoms. Frond production in duckweed was significantly reduced even at the lowest concentration tested, 0.072 ppm.

In standard tests, trinexapac-ethyl proved practically nontoxic to bees exposed via oral or contact routes. The substance also proved nontoxic to earthworms, with no adverse effects apparent at any test concentration to 93 ppm in a 14 day artificial soil test.

### **Environmental Hazard**

Trinexapac-ethyl will be mostly taken up by vegetation following application. Residues that are not so intercepted will mainly become associated with interstitial water in the soil, where they are mobile but subject to rapid microbial degradation.

Trinexapac-ethyl is practically non-toxic to birds and mammals. Residues on turfgrass immediately after spraying at the highest proposed rate (1 kg.ha<sup>-1</sup> ai) would be around 200 ppm, well within dietary no effect levels.

As noted above, trinexapac-ethyl is moderately toxic to fish fry. If sprayed inadvertently over 15 cm of standing water at the maximum proposed rate, a concentration of about 0.7 mg.L<sup>-1</sup> would prevail, in the same order as threshold concentrations above which growth impairment was observed in the 35 d embryo/larvae study.

Trinexapac-ethyl will be applied infrequently and is non-persistent. Therefore, comparison with acute end-points is more relevant to the likely environmental exposure. The predicted environmental concentration from direct overspray is an order of magnitude below the LC<sub>50</sub> for the highly sensitive mysid shrimp. Larger safety margins prevail for freshwater organisms.

The above concentration would be in excess of EC<sub>50</sub> values for growth inhibition of bluegreen algae and duckweed. However, trinexapac-ethyl will be applied in terrestrial situations, where it is rapidly absorbed by turfgrass. The labels contain warnings not to apply if rain is imminent, not to irrigate for at least one hour after application, and not to apply to waterlogged areas. These measures should ensure that concentrations in runoff are minimised.

Hazard to non-target vegetation appears relatively low as trinexapac-ethyl's plant growth regulating effects appear to be mainly restricted to grass species. Significant exposure of non-target native grasses is not expected as trinexapac-ethyl is rapidly absorbed by turf, and the labels contain warnings that minimise the potential for runoff to occur.

## **PUBLIC HEALTH AND SAFETY ASSESSMENT**

### **Evaluation of Toxicology**

The toxicological database for trinexapac-ethyl which consists primarily of toxicity tests conducted using animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses which are high compared to likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observable-Effect-Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

### **Toxicokinetics and Metabolism**

At least 90% of an oral dose of trinexapac-ethyl was absorbed in rats but was eliminated rapidly. Excretion mainly occurred via the urine. After 7 days, only low

residue levels of trinexapac-ethyl were found in the tissues. This indicates that trinexapac-ethyl has a low potential to accumulate on chronic exposure.

#### Acute Studies

Trinexapac-ethyl was of low oral, dermal and inhalational toxicity in rats. Estimated oral lethal doses are of the order of 2000-5000 mg/kg body wt. It was a slight skin and eye irritant in rabbits, but was not a skin sensitiser in guinea pigs.

Acute toxicity studies on formulation having the same trinexapac-ethyl concentrations as PRIMO 250 EC indicated low oral and inhalational toxicity. Skin and eye irritancy potential of formulated products are influenced by the non-active ingredients and, while no data were provided on the specific formulations proposed to be marketed in Australia, the toxicity profile of one of the solvents suggests that there could be moderate irritancy potential. The labels will carry appropriate warnings and safety directions to avoid skin and eye contact.

#### Short-term Studies

Short-term (up to 90 days) dietary administration of trinexapac-ethyl to rats at doses above 300 mg/kg/day resulted in toxic effects on the liver, kidney and heart. The most significant effects were alterations in serum biochemical parameters and increases in organ weights which were indicative of mild liver and kidney toxicity. There was also some evidence of weight variation and mild inflammatory lesions in the hearts of treated rats. In dogs, dietary administration of trinexapac-ethyl resulted in decreased heart and popliteal lymph node weights at 870 and 2 mg/kg/d respectively, and atrophy of the thymus at 870 mg/kg/d. The significance of the effects on the lymph nodes was difficult to determine since this was not observed in another study using dogs treated with comparable doses for up to one year.

In rabbits which had trinexapac-ethyl applied to the skin under occlusive dressings at doses of 10 - 1000 mg/kg body wt/day for 21 days, dermal irritation at the site of administration was the only observable toxic effect and there was no evidence of toxicity to internal organs.

#### Long-term Studies

Long-term dietary administration of trinexapac-ethyl in mice resulted in changes in white blood cell counts at 912 mg/kg body wt/day. In rats high dietary doses over 2 years resulted in a marginal increase in the incidence of stomach and skin tumours at 805 and 494 mg/kg body wt/day respectively. While it appeared that the tumours could have been related to treatment with trinexapac-ethyl, this was by no means certain. There was also an increase in the incidence of haemorrhage of the brain at 805 mg/kg body wt/day and these lesions were probably associated with pituitary tumours. However, pituitary tumours occur commonly in rats and the effects were only observed at the highest dose level and only in female rats, so the relevance to treatment with trinexapac-ethyl was again not clear. Whatever the relevance of these effects to treatment with trinexapac-ethyl, they only occurred at doses which greatly

exceed any potential human exposure that may result from the proposed uses of PRIMO 250 EC.

The most sensitive species was the dog. Brain lesions indicative of slight toxicity were observed in some dogs treated for 1 year at 357 mg/kg body wt/day, but decreased testes and uterine weights were the most sensitive indicators of toxicity, with a NOEL of 1.4 mg/kg body wt/day.

#### Reproduction and Developmental Studies

Dietary administration of trinexapac-ethyl to rats at high doses over two generations did not affect fertility, however, toxic effects on offspring were apparent at 1000 mg/kg body wt/day and consisted of reduced pup survival and reduced pup body weights. These effects were most likely due to reductions in maternal body weight and food consumption. In pregnant rats and rabbits that were given trinexapac-ethyl orally, there was no evidence for a potential to cause birth defects.

#### Genotoxicity

A number of tests established that trinexapac-ethyl does not damage genetic material (DNA). Studies submitted consisted of tests for mutagenicity in '*S.typhimurium*' strains and Chinese hamster lung cells, chromosomal effects in human lymphocytes and mouse bone marrow cells, and unscheduled DNA synthesis in rat hepatocytes and human fibroblasts.

#### Other Studies

On the basis of computer modelling, dermal exposure levels to trinexapac-ethyl were reduced if workers wore suitable clothing; inhalational exposure levels were estimated to be low.

Residues of trinexapac-ethyl on treated turf fell rapidly, with no residue detected after 31 days. Although some exposure to residues may occur from persons coming in contact with treated turf, dermal exposure levels are expected to be well below thresholds for toxicity and to decrease with time.

**Potential for Residues in food for humans**

Based on an assessment of the toxicology and the fact that there should be no dietary intake of residues of trinexapac-ethyl, it was considered that there should be no adverse effects on human health from the use of PRIMO 250 EC for the regulation of turf growth according to label instructions.

The applicant was required to incorporate the warning statement on label

**DO NOT GRAZE TREATED TURF/LAWN OR FEED TURF/LAWN CLIPPINGS  
FROM ANY TREATED AREA TO POULTRY OR LIVESTOCK**

**Public Health Standards**

The National Drugs and Poisons Schedule Committee (NDPSC) considered the toxicity of the product and its active ingredients and assessed the necessary controls to be implemented under States' poisons regulations to prevent the occurrence of poisoning.

The NDPSC recommended that trinexapac-ethyl be listed in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). There are provisions for appropriate warning statements and first-aid directions on the product label.

**OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT**

Trinexapac-ethyl is not a hazardous substance according to Worksafe Australia. PRIMO 250 EC TURF GROWTH REGULATOR has been classified as a hazardous substance by Worksafe Australia according to the National Occupational Health and Safety Commission (NOHSC) Approved Criteria for Classifying Hazardous Substances.

Workers involved in formulation and packaging of the product should be protected by engineering controls, such as ventilation and by the observance of safe work practices, including the containment of spills. Formulation workers and packers are to wear gloves, eye protection, PVC apron and dust mask as an added precaution to reduce exposure to the active constituent and other ingredients in the formulation.

Potential for contamination with the product during transport, storage and retailing is only likely in the case of accidental spillage. The Safe Handling Information in the Material Safety Data Sheet (MSDS) is adequate to enable these workers to minimise exposure in this situation.

End users will handle the trinexapac-ethyl product when preparing and using the spray. It is possible they may experience some skin contact with the product.

However the likelihood of experiencing acute and chronic health effects is low as long as label safety directions are followed.

The product label specifies the use of cotton overalls, washable hat, elbow-length PVC gloves and face shield or goggles and personal hygiene advice to enable end users to minimise contact with the product.

The company has proposed the following restricted entry statement on the label for PRIMO 250 EC TURF GROWTH REGULATOR “ Do not enter treated areas without protective clothing until spray has dried”. Worksafe Australia does not propose any additional restricted entry statements.

Trinexapac-ethyl and PRIMO 250 EC TURF GROWTH REGULATOR can be used safely with the control measures described above.

### **Labelling**

The proposed label for PRIMO 250 EC TURF GROWTH REGULATOR is attached as Appendix 1.

### **SUGGESTED FURTHER READING**

*Interim Requirements for Clearance of Agricultural and Veterinary Chemical Products* (available from the NRA)

*Code of Practice for Labelling Agricultural Chemical Products* (available from the NRA)

*Code of Practice for Labelling Veterinary Chemical Products* (available from the NRA)

*MRL Standard- Maximum Residue Limits in Food and Animal Feedstuffs* (NH&MRC)